



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/709,131

11/10/2000

Ronald B. Gartenhaus

056304.00000

4043

26712 7590 06/23/2009

HODGSON RUSS LLP
THE GUARANTY BUILDING
140 PEARL STREET
SUITE 100
BUFFALO, NY 14202-4040

EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

06/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/709,131	GARTENHAUS, RONALD B.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Exhibits A and B</u> |

DETAILED ACTION

RE: Gartenhaus

1. The finality of the previous office action is withdrawn and prosecution on the merits continues.
2. Applicant's response filed on 5/28/2009 is acknowledged. Claims 32, 36 and 37 are pending. Claims 1-31, 33-35 and 38-48 have been cancelled.
3. Claims 32, 36, and 37 are under examination.

Rejections Withdrawn

4. The rejection of claims 32, 36, and 37 under 35 USC 101 because the claimed invention lacks patentable utility is withdrawn in view of applicant's persuasive arguments and upon further consideration.
5. The rejection of claims 32, 36, and 37 under 35 USC 112, first paragraph as failing to comply with the enablement requirement is withdrawn in view of applicant's persuasive arguments and upon further consideration.

Priority

6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/085,029, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

The instant claims 32, 36 and 37 are drawn to an antibody which binds with specificity to a protein comprising the sequence of SEQ ID NO:8. The SEQ ID NO:8 is not disclosed in Application No. 60/085,029. Accordingly, the claims are given the priority date of the PCT/US99/10184 (i.e. 5/10/1999).

If applicant believes that support for the claims is present in the earliest filed priority document, applicant must, in responding to this action, point out with particularity, where such support may be found.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 32, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards et al. (US 6,783,961B1, Date of Patent: 8/31/2004, earliest effective filing date: 2/26/1999).

Edwards et al teach an isolated antibody capable of specifically binding to a polypeptide comprising a sequence selected from the group consisting of SEQ ID NO: 4101-8177, wherein the antibody is monoclonal antibody (see column 14, lines 35-47). The amino acid sequence of SEQ ID NO:5030 is 100% identical to the residue 1-94 of the instant SEQ ID NO:8 (see sequence alignment Exhibit A). An antibody that binds SEQ ID NO:5030 would also bind the instant SEQ ID NO:8.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 32, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prosniak et al. (Cancer Res., 1998, Oct., 58:4233-4237), in view of Young et al. (US 6,153,740, Date of Patent: 11/28/2000, earliest effective filing date at least 2/13/1997).

Prosniak et al. teach a novel candidate oncogene MCT-1 that is involved in cell cycle progression (see abstract). Prosniak et al. disclose that ongoing studies examining the interaction of MCT-1 with other molecule, including regulatory component of the G1-S phase of the cell cycle, will help elucidate the mechanism through which it accelerates cell cycle progression, and evaluation the amplification and expression of MCT-1 in a range of human tumors will further delineate its contribution to tumor development (see page 4237, last paragraph). The amino acid sequence of MCT-1 (see Figure 1) is 100% identical to the instant SEQ ID NO:8 (see sequence alignment Exhibit B).

Prosniak et al. do not disclose an isolated monoclonal antibody that binds specifically to the MCT-1 protein. However, these deficiencies are made up for in the teachings of Young et al.

Young et al. disclose that methods based on the use of a novel cDNA sequence for expressing the cDNA to produce the encoded protein, and raising antibodies including monoclonal antibodies to the expressed protein were well known in the art (see column 18, lines 1-14, and column 10, lines 1-10).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced an anti-MCT-1 monoclonal antibody for the purpose of study of the mechanism of MCT-1 on cell cycle progression and tumor development in view of Prosniak. One would have been motivated to do so because Prosniak et al. teach that studies examining the interaction of MCT-1 with other molecule, including regulatory component of the G1-S phase of the cell cycle, will help

elucidate the mechanism through which it accelerates cell cycle progression, and evaluation the amplification and expression of MCT-1 in a range of human tumors will further delineate its contribution to tumor development (see page 4237, last paragraph). One of ordinary skill in the art would have a reasonable expectation of success to have produced an anti-MCT-1 monoclonal antibody because method of making a monoclonal antibody based on a gene sequence was well known in the art, as shown by Young et al.

Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Application/Control Number: 09/709,131
Art Unit: 1643

Page 7

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643